UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,796	07/06/2004	Gwong-Jen J Chang	6395-64909-02	5091

46135 7590 09/11/2007

KLARQUIST SPARKMAN, LLP
121 S.W. SALMON STREET
SUITE 1600
PORTLAND, OR 97204

EXAMINER	
PARKIN, JEFFREY S	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
09/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,796	CHANG, GWONG-JEN J	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *18-27,29,31,33,35 and 37-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,28,30,32,34,36 and 44-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07/06/2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *see attached*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply...*.

Detailed Office Action

Status of the Claims

Applicant's election of Group I, with traverse, in the communication received 29 May, 2007, is noted. Applicant argues that the claims share unity of invention and should all be rejoined. This argument is not persuasive. Applicant is correct in noting that this application was filed under 35 U.S.C. § 371 and is subject to unity of invention practice pursuant to 35 U.S.C. § 121 and 372. However, contrary to applicant's assertion, the inventions listed as Groups I-VII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the claimed invention fails to make a contribution over the prior art (i.e., see the ISA Chapter I search report). Applicant also requested rejoinder of Groups I and II in the event the restriction was maintained. Upon further review the examiner has agreed to rejoin Groups I and II. Applicant's comments regarding rejoinder of Group III in the event allowable subject matter is identified is also noted. Thus, claims 1-17, 28, 30, 32, 34, 36, as well as, new claims 44-54 are currently under examination. Claims 18-27, 29, 31, 33, 35, and 37-43 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

37 C.F.R. § 1.98

The information disclosure statements filed 26 November, 2004, 13 June, 2005, and 26 June, 2006, have been placed in the

application file and the information referred to therein has been considered.

37 C.F.R. § 1.821-1.825

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2) (e.g., see Figure 2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicants are reminded that sequences appearing in the specification and/or **drawings** must be identified by a sequence identifier (SEQ ID NO.:) in accordance with 37 C.F.R. § 1.821(d). Applicant must provide appropriate amendments to the specification and/or drawings inserting the required sequence identifiers. Extensive amendments may necessitate the submission of a substitute specification. If sequence identifiers have already been provided for p14DV389 and pc14DV2453, applicants may simply amend the figure descriptions to reference those relevant portions of the sequence identifiers (e.g., nucleotides 1-49 of SEQ ID NO.: X).

37 C.F.R. § 1.121

The drawings are objected to because they fail to comply with 37 C.F.R. § 1.821-1.825 (see Figure 2). Applicants are reminded that sequences appearing in the specification and/or drawings must be identified by a sequence identifier (SEQ ID NO.:) in accordance with 37 C.F.R. § 1.821(d). Applicant must provide appropriate amendments to the specification and/or drawings

inserting the required sequence identifiers. Extensive amendments may necessitate the submission of a substitute specification. If sequence identifiers have already been provided for p14DV389 and pc14DV2453, applicants may simply amend the figure descriptions to reference those relevant portions of the sequence identifiers (e.g., nucleotides 1-49 of SEQ ID NO.: X). Corrected drawing sheets in compliance with 37 C.F.R. § 1.121(d) may be required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 C.F.R. § 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

35 U.S.C. 120

Applicant's benefit claim under 35 U.S.C. § 120 is confusing. The first paragraph of the application references one lineage of applications while the preliminary amendment filed 06 July,

2004, provides another. Applicant should clearly identify those applications that are being relied upon for priority and the first paragraph of the specification should be amended appropriately to remove any ambiguities. For the purposes of applying prior art, the examiner will use the priority claim set forth in the oath/declaration and preliminary amendment which would provide an effective filing date of 04 April, 2001. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. § 120, a specific reference to the prior-filed application in compliance with 37 C.F.R. § 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. § 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. If the instant application is a utility or plant application filed under 35 U.S.C. § 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. § 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. § 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 C.F.R. § 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. § 119(e) and/or 120, where applicable, within this

time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. § 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. § 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. § 120 or 119(e) and 37 C.F.R. § 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 C.F.R. § 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 C.F.R. § 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. If the reference to the prior application was previously submitted within the time period set forth in 37 C.F.R. § 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 C.F.R. § 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 C.F.R. § 1.78(a) and the surcharge under 37 C.F.R. § 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 C.F.R. § 1.78(a) by filling an amendment to the first sentence(s) of the specification or an ADS. See M.P.E.P. § 201.11.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50-52 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claims reference carboxyl terminal chimeric E protein truncations wherein said truncations are "about" 5%, 10%, 15%, etc. This is a relative term and fails to clearly set forth the metes and bounds of the patent protection desired. For instance, does "about" 5% comprise 3%, 4%, 4.5%, 4.8%, 5.1%, 5.5%, 6%, 7%, etc. Clearly this limitation fails to set forth the precise characteristics being claimed. Appropriate correction is required (i.e., wherein the carboxy terminal portion is 5% of the chimeric E protein).

35 U.S.C. § 101

The following is a quotation of 35 U.S.C. § 101 which reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a

patent therefore, subject to the conditions and requirements of this title.

Claim 16 is rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. The term "cell" as defined by the specification at page 21, lines 11-25, encompasses human cells that have been administered the claimed nucleic acids and therefore become an inseparable part of the human itself. Thus the scope of the claim encompasses a human being, which is non-statutory subject matter. As such, the recitation of the limitation "isolated" or "purified" would be remedial. See 1077 O.G. 24, April 21, 1987.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 8-10, 12, and 16 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Pletnev *et al.* (1992). Pletnev and colleagues provide isolated nucleic acids encoding chimeric flaviviruses comprising a structural protein signal sequence from a first flavivirus and a second flavivirus antigen (see abstract, p. 10532; Table 1, p. 10534). This teaching clearly meets all of the claimed limitations.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-17, 28, 30, 32, 34, 36, and 44-54 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yasui *et al.* (1990) in view of Kochel *et al.* (2002), Ivy *et al.* (2000), Phillpotts et al. (1996), and Kozak (1987). The claims are directed toward nucleic acids encoding recombinant chimeric flaviviruses comprising a structural protein signal sequence of a first flavivirus and a second antigen from another flavivirus. The claims also stipulate that the constructs of interest have a CMV-IE promoter and Kozak consensus sequence.

As previously set forth, Yasui and colleagues describe the preparation of recombinant baculovirus and vaccinia virus expression vectors encoding the prM, E, and NS1 proteins of the Japanese encephalitis virus (JEV). Expression cassettes were prepared comprising signal sequences and the respective genes

under the control of various promoters. The authors reported (see Abstract, p. 663) that "PrM and E proteins which had predictable signal sequences upstream on the N terminals were expressed with antigenically active form and molecular size the same as the authentic ones by the recombinant viruses. However, the recombinant viruses which had no such signal sequence expressed unprocessed proteins with antigenically denatured forms. These results suggest that normal proteolytic processing is needed to construct biologically active structures of JEV structural proteins." This teaching does not disclose constructs encoding a signal sequence from a first flavivirus and a second flavivirus immunogen.

Kochel and associates describe the preparation of nucleic acid dengue virus vaccines comprising a nucleic acid encoding the prM signal sequence and the envelope protein. These genes may be from the same isolate or different isolates. This teaching does not disclose the utilization of a JEV prM signal sequence or signal and antigen sequences from non-DEN coding regions.

Ivy and colleagues describe the preparation of nucleic acid constructs comprising a first nucleotide sequence encoding a signal sequence and a second nucleotide sequence encoding the E antigen of any given flavivirus (e.g., dengue, JEV, TBE, YFV, WNV, or SEV). The signal sequence may consist of either the $htPA_L$ leader sequence or the prM leader sequence.

Philpotts and colleagues provide constructs comprising the CMV-IE promoter and SLE viral antigens.

Finally, Kozak provides consensus sequences for translational initiation.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was

made to prepare an expression cassette encoding the prM signal sequence and a flavivirus immunogen (e.g., Env) as taught by Yasui *et al.* (1990), and to substitute immunogenic sequences from other flaviviruses, as suggested by Kochel *et al.* (2002) and Ivy *et al.* (2000), since this expression cassette would provide a facile means for inducing immune responses against the flavivirus of interest. One of ordinary skill in the art would have also been motivated to employ the CMV-IE promoter and SLE immunogens of Phillpotts because the CMV-IE is an efficient promoter and SLE is a viable flavivirus target. One of ordinary skill in the art would have also been motivated to employ the ribosomal translational initiation sequences provided by Kozak since this would reasonably be expected to increase expression.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile

Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

03 September, 20007

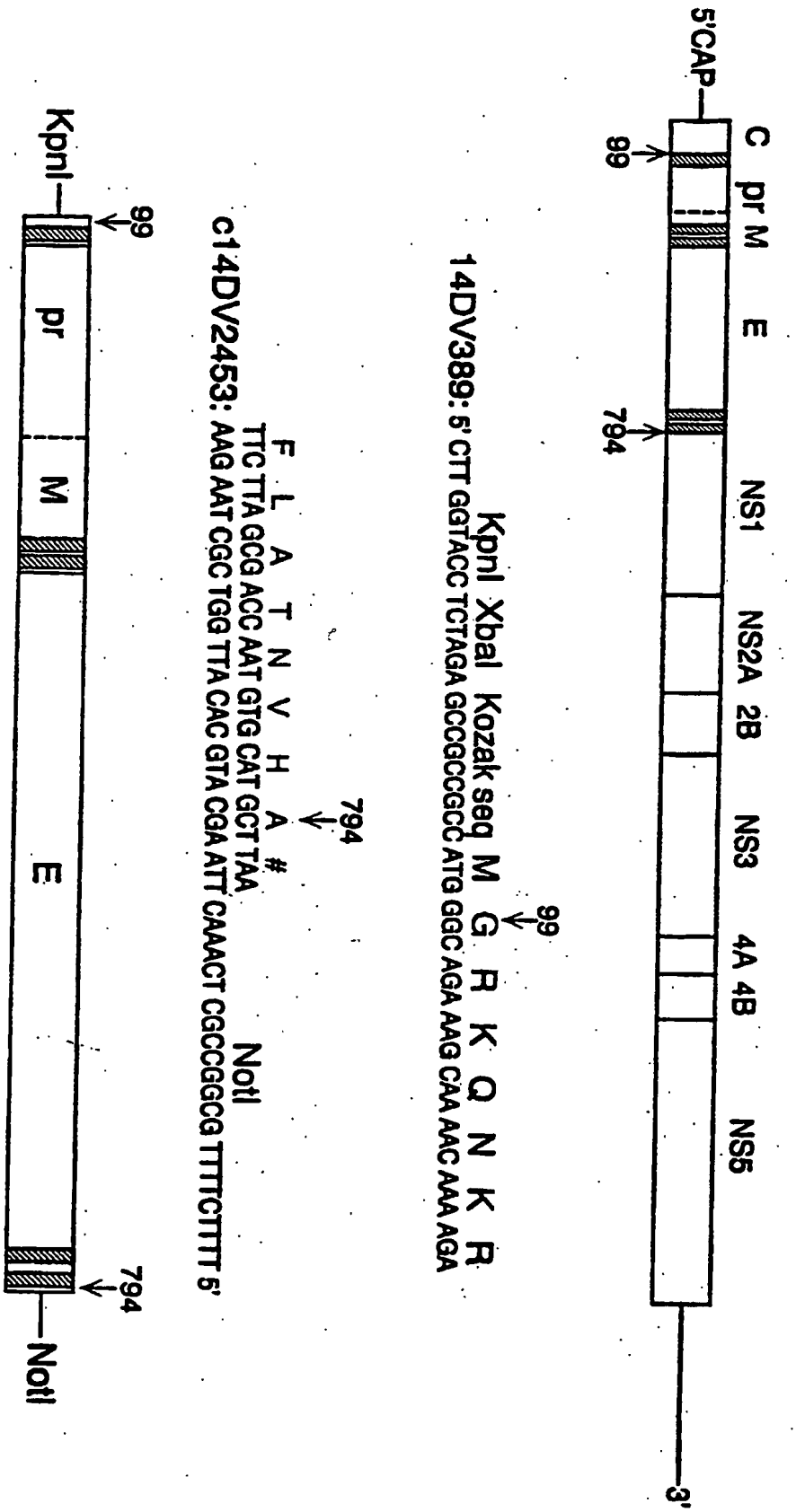
5'CAP
C
pr
M
E
NS1
NS2A
2B
NS3
4A
4B
NS5
3'
99
794
KpnI XbaI Kozak seq M G R K Q N K R
14DV389: 5' CTT GGTACC TCTAGA GCCGCCGCC ATG GGC AGA AAG CAA AAC AAA AGA
99
F L A T N V H A #
794
TTC TTA GCG ACC AAT GTG CAT GCT TAA
c14DV2453: AAG AAT CGC TGG TTA CAC GTA CGA ATT CAAACT CGCCGGCG TTTTCTTTT 5'
NotI
KpnI
99
pr
M
E
794
NotI

Fig. 2

Notice to Comply	Application No. 10/500,796	Applicant(s) Chang, G. J.	
	Examiner Jeffrey S. Parkin	Art Unit 1648	Paper No. 09/03/2007

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: Applicants are reminded that sequences appearing in the specification and/or **drawings** must be identified by a sequence identifier (SEQ ID NO.:) in accordance with 37 C.F.R. 1.821(d). Sequence identifiers for sequences appearing in the drawings may appear in the Brief Description of the Drawings. Applicant must provide appropriate amendments to the specification and/or drawings inserting the required sequence identifiers. Extensive amendments may necessitate the submission of a substitute specification and drawings.

Applicant May Need to Provide:

☒ An substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov.

To Download Patentin Software, visit http://www.uspto.gov/web/patents/software.htm.

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY